DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs; Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA revises the description of growing cattle fed monensin Type C medicated feeds for increased rate of weight gain and for prevention and control of coccidiosis.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: *edubbin@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 95–735 that provides for the use of RUMENSIN 80 (monensin sodium) Type A medicated article. The supplemental NADA revises the description of growing cattle fed monensin Type C medicated feeds for increased rate of weight gain and for prevention and control of coccidiosis. The supplemental NADA is approved as of November 18, 2005, and the regulations in 21 CFR 558.355 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. In § 558.355, in paragraph (f)(3)(iii)(*b*), remove "Feed to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers)."; and revise paragraphs (f)(3)(iii)(*a*), (f)(3)(x)(*a*), and (f)(3)(x)(*c*) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(iii) * * *

(a) *Indications for use.* Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii.*

* * * * *

(x) * * *

(a) *Indications for use.* Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii.*

* * * * *

(c) *Limitations.* Feed at a rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using the monensin mineral supplement. The product's effectiveness in cull cows

and bulls has not been established. Consumption by unapproved species may result in toxic reactions.

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Dated: December 14, 2005

December 14, 2005.

Steven D. Vaughn,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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